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10/807,489

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EXAMINER

LILLING, HERBERT J

ART UNIT

PAPER NUMBER

1657

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/807,489

Applicant(s)

NISHIZAWA ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-17 and 22-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 7-17 and 22-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. The prior restriction and election requirements have been withdrawn in view of the amended claims and the remark by Applicant submitted on June 08, 2007.

2. Claims 7-17 and 22-34 are pending in this application.

Claims 1-6 and 18-21 have been cancelled. Applicant reserves the right to file divisionals to the non-elected cancelled claims.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 7-15, 17 and 22-33, drawn to an electrode comprising a mediator, said mediator comprising a quinone molecule derivative, wherein the mediator is immobilized and the mediator mediates electron transfer between an at least one enzyme and an electrode. classified in class 204, subclass 403.04.
- II. Claims 16 and 34, drawn to an electrode according to claim 7 in combination with an oxygen separation membrane arranged in a vicinity of the mediator which contains at least three enzymes, which classified in class 204, subclass 403.05.

Invention I does not require the specifics of Invention II.

The search and examination for both of the inventions would be extremely burdensome in view of the above differences as well as the search would involve difficult classification as noted by the above subclass differences. The search

Be a serious burden on the Examiner given the claimed subject matter in view of the M.P.E.P. which supports a prima facie case of reasons for a serious burden exists in this application drawn to the two sets of claims based on the following facts:

There is a serious burden as indicated by the fact each of the groups for each of the inventions has **separate classification** as noted above that is sufficient prima facie evidence of a serious burden to examine all of the above inventions drawn to different separate classification as defined in MPEP 808.02 since this clearly indicates that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search.

A different field of search which includes also computerized searches:

Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes /subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims.

The search and examination of the multiple inventions would be a serious burden on this Examiner in view of the additional inventions that **involves different computer searches for each of the different inventions.**

The M.P.E.P. indicates that a serious burden may be established on a different field of search if it is necessary to search for one of the inventions in a manner not likely to result in finding art pertinent to the other invention which includes (a) searching

Art Unit: 1657

different classes and different subclasses; searching different electronic resources or employing different search queries.

Examiner will examine both Inventions based on the following:

However, if Applicant states on the record the statement with the express admission “that the inventions are obvious over each other within the meaning of 35 U.S.C. 103” and provide the reasons for the obviousness, this Examiner will withdraw the restriction requirement in accordance with the MPEP 803.

4. Applicant is advised that the reply to this requirement to be complete must include invention to be examined even though the requirement be traversed (37 CFR 1.143).

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

5. This application contains claims directed to the following patentably distinct species:

Claim 7 is generic to all of the claims.

A. An electrode comprising a mediator, said mediator comprising a quinone molecule derivative whereby the quinone derivative is selected from the following:

Aa. Which is a naphthoquinone derivative;

Whereby the derivative is:

i. is one or more kinds of a naphthoquinone molecule is one of the following:

ia. Sodium anthraquinone-2-sulfonate
(AQS) derivative

ib. 2-methyl-1,4-naphthoquinone
(VK.sub.3) derivative.

If ib. is selected further election:

xba> 2-methyl-1,4-naphthoquinone
(VK.sub.3) derivative.

Whereby above xba derivative is
selected from the following functional groups:

Xa>amino group,

Xb> a carboxyl group,

Xc> a chloroformyl group,

Xd> a succinimide oxycarbonyl group,

Xe> alkyl metal sulfosuccinimide oxycarbonyl group,

Xf> pentafluorophenyl oxycarbonyl group,

Xg> p-nitrophenyl oxycarbonyl group,

Xh> hydroxyl group,

Xi> formyl group,

XJ> halogen group,

Xk> maleimide group,

Xm> isothiocyanate group,

Xn> oxiranyl group,

Xo> other function group-
please specify

Xp> combination of more than
one functional group-please
specify .

Furthermore whereby the 2-methyl-1,4-naphthoquinon- e (VK3) derivative is one or more kinds of a

quinone molecule selected from the group consisting of :

AA1: 2-(3-carboxypropyl)-3-methyl-1,4-naphthoquinone (CPVK.sub.3) represented by the following formula (1)

AA2: 2-3-[N-(2-aminoethyl)aminocarbonyl]propyl}-3-methyl-1,4-naphthoquinone (AEACPVK.sub.3) represented by the following formula (2),

AA3: 2-(3-aminopropyl)-3-methyl-1,4-naphthoquinone (APVK.sub.3) represented by the following formula (3).

ii. Whereby the naphthoquinone molecule derivative comprises between the functional group and the 2-position of the naphthoquinone:

- a. a spacer molecule which is selected from:
 - aa. hydrocarbon linear chain alkyl group;
 - ab. other-please specify.
- b. no spacer molecule.

Ab. Which is any other quinone derivative-please specify.

Art Unit: 1657

B: Whereby the electrode comprising a mediator, said mediator comprising a quinone molecule derivative, wherein the mediator is immobilized and the mediator mediates electron transfer between an at least:

1. one enzyme and an electrode,
2. two enzymes and an electrode,
3. three enzymes and an electrode,
4. other-please specify and an electrode.

It should be noted that if Applicant elects "at least two enzymes and an electrode" [claim 10] then both claims 8 and 12 will be technically not drawn to the elected species and outside the elected species commensurate in scope with the elected invention for examination purposes. There is absolutely no request to cancel these claims which will be considered based on the examination of the elected species based on the art of record. If no art is found for the "at least two enzymes and an electrode", claim 12 containing "at least three enzymes and an electrode" will also be allowed. If Applicant elects "at least one enzyme and an electrode" [claim 8] and no art is found, both claims 10 and 12 will also be allowed.

C. Whereby the enzyme or enzymes are:

- a. not immobilized;
- b. immobilized
- c. combination of above-please specify.

D. Whereby the enzyme contains:

- x. diaphorase
- y. diaphorase and dehydrogenase
- z. other(s) please specify.

E. Whereby the electrode of above Dx or Dy or Dz:

- a. further comprising NADH immobilized;

b. does not further comprising NADH immobilized.

F. Whereby an electrode comprising an enzyme immobilized comprising the mediator whereby the enzyme is immobilized on the electrode by :

m. both a polymer and a crosslinking agent;

ma. whereby the polymer is:

p. polyvinylimidazole;

q. other polymer-please specify;

and

mb. Whereby the crosslinking agent is:

i. polyethylene glycol diglycidyl ether;

ii. other please specify.

n. only a polymer whereby the polymer is:

na. polyvinylimidazole;

nb. other polymer-please specify.

The species are independent or distinct because each one of the above is distinct from each other and are considered to be patentably distinct from each other. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with

this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The election of species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention.

However, if Applicant states on the record the statement with the express admission “that the species are obvious over each other within the meaning of 35 U.S.C. 103” and provide the reasons for the obviousness of the species, this Examiner will withdraw the election requirement in accordance with the MPEP 803.

6. Furthermore, it is noted that the specification may be found to be fatally defective for the broad claimed inventions involving a quinone molecule derivative whereby the derivative is modified with one or more kinds of a functional group selected from the groups as noted above as Xa-Xp which scope of the description of the molecules cannot be determined. The instant specification may be considered to lack sufficient information as to the modification of the quinone molecule derivatives since the functional groups can be located on any number of atoms and the specification lacks any generic claim indicating the positions and the number of "one or more kinds of a functional group" attached.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

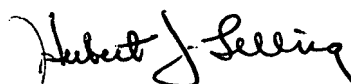
Art Unit: 1657

9. It is noted that Diagram No 1 will be objected to as containing unknown data or remarks in the drawing.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300** or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
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Art Unit **1657**
July 17, 2007



Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657

FIGURE 1

